REMARKS

Claims 1, 5 – 11, 25 and 34 - 37 are pending in the application. Claims 2 - 4, 12 – 24, and 26 – 33 have been canceled. Claims 1, 25, 34 and 36 have been amended. No new claims have been added. No new matter has been added by virtue of the amendments, support being found throughout the specification and the claims as originally filed.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Claim Rejections

35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1, 5 – 11, 25 and 36 under 35 USC §112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse the rejection.

The instant claims recite PNA probes comprising a nucleobase sequence for the detection, identification or quantitation of Pseudomonas, wherein said PNA probe comprises a sequence of 15– 17 nucleobase subunits in length, wherein at least a portion of the probe is at least 90% identical to CCT ACC ACC TTA AAC (SEQ ID NO: 1) or the complement thereof, and wherein said PNA probe is complementary to a target sequence of 23S rRNA or rDNA of Pseudomonas aeruginosa, Pseudomonas alcaligenes, Pseudomonas chlororaphis, Pseudomonas fluorescens, Pseudomonas fragi, Pseudomonas huttiensis, Pseudomonas luteola, Pseudomonas mendocina, Pseudomonas mucidolens, Pseudomonas nitroreducens, Pseudomonas pseudoalcaligenes, Pseudomonas putida, Pseudomonas stutzeri, or Pseudomonas veronii, or sequences complementary to these target sequences.

The Examiner argues that "claims 1 and 5 – 11 are indefinite over the recitation of the limitation 'at least 90% identical to the nucleobase sequence or complement thereof comprising' SEQ ID NO: 1 in independent claim 1." (Office Action, p.3). The Examiner argues that "(t)he claims do not previously refer to a 'nucleobase sequence or complement thereof comprising" SEQ ID NO: 1, accordingly, clear antecedent basis for the recitation 'the nucleobase sequence or complement thereof comprising' SEQ ID NO: 1 is lacking (and) (f)urther, while the claim previously references a 'nucleobase sequence,' interpretation of the language noted above as referring back to the previously recited 'nucleobase sequence for the detection, identification or quantitation of Pseudomonas' creates confusion, as this nucleobase sequence does not have any specific sequence with respect to which percent identity might be calculated." (Office Action, p.3).

The Examiner suggests that the "claim should be amended so as to clearly recite the structural requirements of the sequence or sequences with respect to which percent identity is calculated so as to clearly apprise one of ordinary skill in the art as to what types of probes would and would not be embraced by the claims. The Examiner suggests "the following language would be considered clear and definite:...wherein at least a portion of the probe is at least 90% identical to SEQ ID NO: 1 or the complement thereof." (Office Action, p.3).

Applicants have amended the claims in accordance with the Examiner's suggestions. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner argues that "claim 25 is indefinite over the recitation of the limitation 'at least 90% identical to the nucleobase sequence or complement thereof comprising' SEQ ID NO: 1." (Office Action, p.4). The Examiner argues "(t)he claims do not previously refer to a 'nucleobase sequence or complement thereof comprising" SEQ ID NO: 1, accordingly, clear antecedent basis for the recitation 'the nucleobase sequence or complement thereof comprising' SEQ ID NO: 1 is lacking (and) (f)urther, while the claim previously references a 'nucleobase sequence,' interpretation of the language noted above as referring back to the previously recited 'nucleobase sequence for the detection, identification or quantitation of

Pseudomonas' creates confusion, as this nucleobase sequence does not have any specific sequence with respect to which percent identity might be calculated." (Office Action, p.4).

The Examiner suggests the "claim should be amended so as to clearly recite the structural requirements of the sequence or sequences with respect to which percent identity is calculated so as to clearly apprise one of ordinary skill in the art as to what types of probes would and would not be embraced by the claims. The Examiner suggests that "the following language would be considered clear and definite:...wherein at least a portion of the probe is at least 90% identical to SEQ ID NO: 1 or the complement thereof." (Office Action, p.4).

Applicants have amended the claims in accordance with the Examiner's suggestions. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Examiner argues "claim 36 recites the limitation that 'the PNA probe of claim 34 for the detection, identification and/or quantification of Pseudomonas" in lines 1 – 2 of the claim (and) there is insufficient antecedent basis for this limitation in the claim, because claim 34 does not recite such as probe; rather claim 34 refers to a "PNA probe comprising a nucleobase sequence for the detection, identification or quantitation of Psuedomonas." (Office Action, p.5).

Applicants have amended the claims to recite the PNA probe of claim 34, and instructions for use.

The Examiner indicates the "rejection could be overcome by amending claim 36 to simply recite e.g., 'the PNA probe of claim 34 and instructions for use.'" (Office Action, p.5).

Applicants have amended the claims in accordance with the Examiner's suggestions. Accordingly, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §103(a)

The Examiner has maintained the rejection to claims 1 – 2, 4 – 7, 9 – 12 and 34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ludwig

et al. (Applied Environmental Microbiology 60(9):3236 – 3244) in view of Hyldig-Nielsen et al. (US 6,169,169 B1).

The Examiner has also maintained the rejection to claims 7 - 8 under 35 U.S.C. § 103(a) as being unpatentable over Ludwig et al. (as above) in view of Hyldig-Nielsen et al. (as above), as applied to claims 1 – 2, 4 – 7, 9 – 12 and 34, above, and further in view of Gildea et al. (6,485,901).

The Examiner has rejected claims 25 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Ludwig et al. (as above) in view of Hyldig-Nielsen et al. (as above), as applied to claims 1, 5 – 7, 9 – 11, 34 – 35, 37, above, and further in view of Ahern et al.

For the sake of brevity, the Examiner's rejections under 103(a) are addressed together because each rejection relies on the Ludwig et al. reference in combination with at least one secondary reference.

Applicants respectfully traverse the above rejections.

The claims recite a PNA probe comprising a nucleobase sequence for the detection, identification or quantitation of Pseudomonas, wherein at least a portion of the probe is at least 90% identical to CCT ACC ACC TTA AAC (SEQ ID NO: 1), or the complement thereof. Claim 7 depends from claim 1, and indicates that the probe is self-reporting.

The Examiner argues that Ludwig "disclose 23s rRNA partial sequences for a variety of Pseudomonas species, each of which includes an RNA sequence corresponding to the reverse complement of SEQ ID NO: 1 (and) thus Ludwig inherently disclose that instant SEQ ID NO: 1 exactly complements the 23s rRNA sequence of a variety of (P)seudomonads." (Office Action, p.5). The Examiner notes that "Figure 2 of Ludwig et al. reveals that there are sequence differences between all pseudomonads and a variety of other bacterial species at the region corresponding to instant SEQ ID NO: 1 (and) the teachings of Ludwig et al. suggest that the region of 23S rRNA corresponding to instant SEQ ID NO: 1 is a suitable target for a genus-specific probe for pseudomonads." (Office Action, p. 5 - 6).

The Examiner argues that "Hyldig-Nielsen et al. disclose PNA probes targeting the 23S rRNA or rDNA sequences of Neisseria gonorrhoeae and Chlamydia trachomatis (and) disclose that probe sequences are selected that will hybridize to and identify target organisms of interest." (Office Action, p.6). The Examiner argues that "Hyldig-Nielsen et al. further disclose that PNA probes are advantageous as compared to DNA probes for a variety of reasons" and the Examiner thus concludes that "in view of the teachings of Ludwig et al. and Hyldig-Neilsen et al., it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have prepared a PNA probe comprising SEQ ID NO: 1 for use in detecting one or multiple Pseudomonas species." (Office Action, p.6). The Examiner is of the opinion that "an ordinary artisan would have been motivated to have prepared such a probe for the advantage of, and to achieve the predictable result of, preparing a probe that could be used successfully in the specific detection of pseudomonads in a variety of assay formats and hybridization conditions as suggested by the teachings of Ludwig and Hyldig-Neilsen et al." (Office Action, p.7). Applicants respectfully disagree.

The Ludwig reference fails to teach or suggest all the elements of the instant invention. Ludwig does not teach or suggest **a PNA probe comprising a nucleobase sequence for the detection, identification or quantitation of Pseudomonas**, where the PNA probe is complementary to a target sequence of 23S rRNA or rDNA of the species of the genus of Pseudomonas as instantly claimed. The Ludwig reference does not teach or suggest **a single nucleobase sequence as a suitable target for a genus specific probe for the detection, identification or quantitation of Pseudomonas**.

The Ludwig reference describes "polynucleotide sites on bacterial 23s rRNAs (that) have been tested for their general applicability for group-specific probes." (p.3237). Ludwig (at p.3240) teaches comparative sequence analyses of bacterial 23S rRNA genes that reveal a large evolutionarily only moderately conserved region within domain III of the large subunit rRNA. DNA coding for a variable region within

domain III was used as the target for group-specific hybridization probes. The corresponding rDNA was amplified in vitro and the amplified fragments were sequenced and the primary structures were inserted in an alignment of about 100 complete bacterial 23S rRNA sequences according to primary-structure and predicted secondary structure similarities (p.3240). The aligned partial sequences are shown in Figure 2.

The Examiner argues that "(w)hile the alignment provided by Ludwig illustrates more than one region of identity shared by pseudomonads, this fact would not have dissuaded an ordinary artisan from preparing the probe of the claims; rather an ordinary artisan would have recognized that multiple regions in the alignments of Ludwig (including that of instant SEQ ID NO: 1) would have been good targets for Pseudomonas detection." (Office Action, p.10). The Examiner is of the opinion that "the art must suggest the product itself (as it does in the present case)." (Office Action, p.10). Applicants respectfully disagree.

Applicants have identified a **genus specific probe** that is at least 90% identical to CCT ACC ACC TTA AAC (SEQ ID NO: 1) or the complement thereof, to identify only members of the Pseudomonas genus. The region of 23s rRNA corresponding to SEQ ID NO: 1, when compared to other target regions contemplated for PNA probes for Pseudomonas, shows greater specificity.

The Ludwig reference nowhere teaches or suggests one specific region of 23s rRNA that is suitable for the detection, identification or quantitation of Pseudomonas. Figure 2 is merely an alignment 23s rRNA partial sequences that are over 200 nucleotides long. Ludwig does not provide any guidance or suggestion that there is **one specific probe that detects one specific region**, as taught by the instant invention, of the 23s rRNAs that may be a suitable target for a genus-specific probe for Psuedomonads.

Moreover, the art teaches that no one probe to one specific region of 23s rRNA is known or suggested that can suitably detect, identify or quantitate the genus of Pseudomonas.

Applicants refer the Examiner to the Hyldig-Nielsen reference (US Patent No. 6,664,045; the '045 reference herein), which is different from the Hyldig-Neilsen reference cited by the Examiner, and is used to show that the art in fact teaches that no one probe to one specific region of 23s rRNA is known or suggested that can suitably detect, identify or quantitate the genus of Pseudomonas. The '045 reference teaches that **a set of three probes was required to detect a Pseudomonas genus**. Table 1 (col 10) of the '045 reference shows that **SEQ ID NOs: 7, 8 and 9 were needed in combination** to detect the Pseudomonas genus (shown in Figure 2-I). The '045 reference teaches that "the specificity of the probes must be functionally examined since **sequence alignment analysis does not always produce a target specific probe**." (col 10, line 17, emphasis added).

Accordingly, the art does not teach one probe to one specific region of 23s rRNA is known or suggested that can suitably detect, identify or quantitate the genus of Pseudomonas.

Moreover, it is not enough that Ludwig simply teaches the sequence of the species of interest. The Ludwig reference only includes sequence information for 4 non-Pseudomonas species; without sequence information on other closely related species such as Ralstonia, Stenotrophomonas, Sphingomonas, Brevundimonas, Comamonas (as tested in the instant application) lack of cross-reactions to these species and probe specificity cannot be determined. Accordingly, the Ludwig reference has provided no teaching or suggestion to distinguish any one region of the 23s rRNA sequence from another as being preferred for use as a genus specific probe.

None of the Hyldig-Nielsen, Gildea or Ahearn references as cited by the Examiner does not cure the defects of the Ludwig reference.

Nowhere in the Hyldig-Nielsen reference is there teaching or suggestion of a nucleobase sequence as presently claimed as a suitable target for a genus specific probe for the detection, identification or quantitation of Pseudomonas. Nowhere does the Hyldig-Nielsen reference teach a PNA probe comprising a nucleobase

sequence for the detection, identification or quantitation of Pseudomonas, wherein said PNA probe comprises a sequence of 10 – 17 nucleobase subunits in length, wherein at least a portion of the probe is at least 90% to CCT ACC ACC TTA AAC (Seq. Id. No. 1) or the complement thereof, and wherein said PNA probe is complementary to a target sequence of 23S rRNA or rDNA of a species of a genus of Pseudomonas as claimed. Therefore, the teachings of the cited art, when combined, do not result in the claimed invention.

Accordingly, Applicants request that the foregoing rejections be withdrawn.

CONCLUSION

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105.

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Respectfully submitted,

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